

## REMARKS

Reconsideration of the subject application is respectfully requested.

Claims 1-7, 9-13 and 17-19 were pending as of the Office Action mailing date of April 30, 2010. This Reply is timely filed within the three (3) month time period for reply set forth in the Action.

### **I. REJECTION OF CLAIMS 1, 2, 4, 5, 7, 9-12, and 17-19 UNDER 35 USC 102(e).**

Claims 1, 2, 4, 5, 7, 9-12, and 17-19 have been rejected under 35 USC 102(e) as anticipated by US Pat. Application Pub. No. 2005/0230272 to Lee.

Applicant respectfully traverses this rejection.

The current invention, as now claimed, requires, inter alia:

- a) a nanopore substrate having a plurality of nanopores and alignment marks;
- b) a substantially planar support layer deposited on said nanopore substrate and having a plurality of nanopores corresponding to and aligned with said nanopores of said nanopore substrate (amended claim 1, emphasis added)

Support for this amendment is found in the specification as filed, page 16, lines 10-15.

The claim, as now presented requires alignment marks on the nanopore substrate and support layer constructed and positioned such that the support layer as nanopores corresponding and aligned with the nanopores on the nanopore substrate.

The cited Lee reference is deficient for failing to teach the claimed alignment of the nanopores on the substrate with the nanopores on the support layer.

Applicant respectfully traverses the assertion that Lee anticipates the present invention according to the recently amended claim 1. The significant difference between Lee and the present invention is exemplarily demonstrated in Figures 1A and 1B of Lee. These figures illustrate a substrate material 12 which does not comprises any holes or nanopores **aligned** with the wells 18 generated by the polymeric layer 14 which is layered on the substrate material 12. Covering the wells 18 with a lipid layer 24 in order to generate a cavity which is filled with a fluid medium 25 and a bivalent tether group 26 (the latter to keep the lipid layer 24 in the desired form and distance with respect to the well 18) leads to a closed system. The so-generated cavity is then not any longer accessible from the lower side of the lipid bilayer 24 and any reactive component that shall interact with the lipid bilayer or any reactive component disposed therein has to be present in the moment the lipid bilayer is closing the well 18. It has to be emphasized that Lee et al. don't take significantly care of the substrate material 12, since in Lee paragraph [0037] it is stated that "the substrate material 12 forming the ground of the well 18 is not limited by any type of material used for fabrication".

Therefore, Lee not only fails to anticipate the present invention to align the nanopores of the nanopore substrate with the nanopores of the substantially planar support layer being deposited on said nanopore substrate, but also, as will be discussed below, cannot be used to support an obviousness rejection due to the failure to align the nanopores. This alignment allows to observe the functionality of non-lipid molecules and their interaction with other molecules on larger scale over for example a large number of nanopores offering large number of exchange opportunities for the observation whether distinct and/or suspected interactions actually occurred. Eventually, in biochemical analysis not only a distinct concentration of a "reaction product" is required for proving a distinct interaction but also a minimum absolute number of "reaction products", i.e. in a solution, are required to go beyond the lower detection limit. The question of the concentration can be managed by Lee et al. with their teaching of individual bioreactors for each individual bioreactor, but the question of a minimum absolute quantity of a reaction product is not addressable with the teaching of Lee.

Further, the teaching of Lee et al. is lacking the permanent accessibility of the biologically effective layer from both sides of the layer. This gives rise to the following problem Lee et al. are not able to provide a solution for. Sometimes the biomolecules that can -for example - traverse the biologically effective layer after the incorporation of a promoting molecules, such as an enzyme, have a certain size of their molecular structure that are not appropriate to match the limited dimensions of the wells of Lee et al. Since the biologically effective layer has to be spanned

over the nanopores, it is not possible in any case to expand the dimensions of the wells 18 to the dimension required for the biomolecule to live out its full biological behavior. Consequentially, the test chip of Lee et al. is in this case not an option for evaluating the molecular interaction under vital conditions. Our present invention does not suffer from this disadvantage since on both sides of the biologically effective layer we can provide this required freedom of movement and viability even for molecules having a length larger than the diameter and/or the depth of the nanopores.

The assay chip of the present invention has the structure and configuration that allows the study under vital conditions.

Thus, Lee is not anticipatory and in fact is contrary to the system of the present invention.

Applicant reminds the Office:

"[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Claim 1 is respectfully asserted not anticipated by the reference because claim requires, at least, a nanopore substrate having a plurality of nanopores and alignment marks; and a substantially planar support layer deposited on said

nanopore substrate and having a plurality of nanopores corresponding to and aligned with said nanopores of said nanopore substrate, as now claimed.

Because of the failure of the Lee reference to teach each and every element of the claimed invention, Applicant asserts a rejection under 35 USC §102 cannot be properly applied.

Applicant respectfully requests reconsideration and withdrawal of this rejection.

## II. REJECTIONS UNDER 35 USC §103

The current Office Action has set forth two rejections under 35 USC §103. Each rejection will be addressed below.

### A. REJECTION OF CLAIM 3

The current Office Action, on page 5, has rejected claim 3 as being obvious over the Lee reference discussed above in sec I, in view of U.S. patent application publication No. 2004/0120854 to Heath.

Applicant respectfully traverses this rejection.

As stated above in sec I, the subject invention requires alignment marks on the nanopore substrate and support layer constructed and positioned such that the

support layer as nanopores corresponding and aligned with the nanopores on the nanopore substrate.

The cited Lee reference is deficient for failing to teach, suggest, or provide any motivation to modify in order to arrive at the claimed alignment of the nanopores on the substrate with the nanopores on the support layer. Combination of Lee with Heath into a single disclosure fails to cure the deficiency because Heath is only cited to teach the composition being of silicon nitride and silicon dioxide. Lee and Heath, when taken in combination, only teach an article with non-aligned nanopores containing a layer of silicon nitride and silicon dioxide. Thus, the combined disclosure of Lee and Heath is still deficient for failing to teach or suggest the alignment marks on the nanopore substrate and support layer constructed and positioned such that the support layer as nanopores corresponding and aligned with the nanopores on the nanopore substrate.

Because of the failure of the combined Lee and Heath references to teach, suggest, or provide motivation to modify in order to arrive at the subject invention as now claimed, Applicant asserts a rejection under 35 USC §103(a) cannot be properly applied.

Applicant respectfully requests reconsideration and withdrawal of this rejection.

**B. REJECTION OF CLAIM 6**

The current Office Action, on page 5, has rejected claim 3 as being obvious over the Lee reference discussed above in sec I, in view of U.S. Pat. No. 5,843,767 to Beattie.

Applicant respectfully traverses this rejection.

As stated above in sec I, the subject invention requires alignment marks on the nanopore substrate and support layer constructed and positioned such that the support layer as nanopores corresponding and aligned with the nanopores on the nanopore substrate.

The cited Lee reference is deficient for failing to teach, suggest, or provide any motivation to modify in order to arrive at the claimed alignment of the nanopores on the substrate with the nanopores on the support layer. Combination of Lee with Beattie into a single disclosure fails to cure the deficiency because Beattie is only cited in the Office Action to teach the area measurements, diameters, and density array. Lee and Beattie, when taken in combination, only teach an article with non-aligned nanopores having area measurements, diameters, and density array. Thus, the combined disclosure of Lee and Heath is still deficient for failing to teach or suggest the alignment marks on the nanopore substrate and support layer constructed and positioned such that the support layer as nanopores corresponding and aligned with the nanopores on the nanopore substrate.

Because of the failure of the combined Lee and Beattie references to teach, suggest, or provide motivation to modify in order to arrive at the subject invention as now claimed, Applicant asserts a rejection under 35 USC §103(a) cannot be properly applied.

Applicant respectfully requests reconsideration and withdrawal of this rejection.

Please charge any fees that might be due with respect to Sections 1.16 and 1.17 to Deposit Account Number 12-1099 of Lerner Greenberg Sterner LLP.

Respectfully submitted,

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